

Appln. No. 10/574,934
Amdt. dated February 22, 2010
Reply to Office Action dated November 24, 2009
and Advisory Action of January 27, 2010

REMARKS

The Office Action of November 24, 2009, and the Advisory Action of January 27, 2010, have been carefully studied. Claims 17, 20 and 26-34 currently appear in this application. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration and formal allowance of the claims.

Claim Amendments

Claims 17 and 31 have been amended to limit the composition to one administered to a living body, which composition is prepared by mixing (i) an isolated saccharide derivative of L-ascorbic acid, (ii) an isolated 10-hydroxy-2-decenoic acid to enhance the collagen production by (i), and (iii) a physiologically acceptable carrier. Support for these amendments can be found in the specification as filed at page 13, lines 9-13 and Examples 1-3.

The phrase “free of gluconic acid” has been deleted.

The limitation “in said isolated saccharide derivative of L-ascorbic acid” has been inserted after “L-ascorbic acid” to provide sufficient antecedent basis for “L-ascorbic acid” and to clarify that the L-ascorbic acid is part of the saccharide derivative of L-ascorbic acid.

Claim 28 has been amended to correct the term “cosmeti” to – cosmetic--.

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In the Advisory Action m, the Examiner states that "isolated derivatives of L-ascorbic acid" is new matter. However, it is clear from the specification that "isolated derivatives of L-ascorbic acid" is not new matter because the L-ascorbic acid derivatives are commercial products, which one skilled in the art would understand to be pure, or isolated, products.

Support for the recitation "isolated derivatives of L-ascorbic acid" can be found in the specification as filed at page 13, lines 9-18 and Examiner 1-3. Page 13 recites as follows, "To prepare composition containing the agent of the present invention, they are prepared by mixing adequate amount of L-ascorbic acids and fatty acids and optionally an adequate amount of the already mentioned one or more ingredients selected form materials for food products..."

Furthermore, Experiment 1, beginning at page 18, of the specification, relates to **separation and identification** of ingredients from royal jelly that are capable of enhancing collagen production. The purified ingredient was 10-HAD.

Examples 1-3 uses L-ascorbic acid 2-glucoside, "AA2G", a product made and commercialized by Hayashibara Biochemical Laboratories, Inc., Okayama, Japan. One skilled in the art would readily assume that this product is isolated L-ascorbic acid 2-glucoside, as one would expect that a commercial product marketed as a compound *per se* would be isolated, i.e., free of other compounds or impurities.

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Submitted herewith is a copy of "Business Information" describing AA2G L-ascorbic acid 2-glucoside, manufactured by Hayashibara Biochemical Laboratories. Page 2 of this printout states that the company "successfully synthesized" L-ascorbic acid 2-glucoside. Clearly, this is an isolated compound.

Rejections under 35 U.S.C. 112

Claims 17, 20 and 26-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that there is no disclosure of a composition free of gluconic acid.

This rejection is respectfully traversed.

Claims 17 and 31, from which the remaining claims depend, have been amended to delete "free of gluconic acid." Claims 33 and 34 use the term "consisting of", which excludes gluconic acid from the composition.

Claims 17, 20 and 26-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner notes that there is insufficient antecedent basis for the limitation "L-ascorbic acid" in claims 17 and 31.

This rejection is respectfully traversed.

Claims 17 and 31 have been amended to provide sufficient antecedent basis for "L-ascorbic acid." It is clear from amended claims 17 and 31 that the amount of L-ascorbic acid is the amount of L-ascorbic acid present in the isolated saccharide derivative of L-ascorbic acid. That is, the saccharide derivative of L-ascorbic acid is made of a saccharide molecule and an L-ascorbic acid molecule. Thus, there is sufficient antecedent basis for the recitation of "L-ascorbic acid."

With respect to the recitation "in terms of the weight of L-ascorbic acid in said isolated saccharide derivative of L-ascorbic acid to the total weight of said composition," attention is directed to the specification at page 5, lines 18-26:

...the amount of L-ascorbic acids to be incorporated into the agent for enhancing collagen production of the present invention, usually L-ascorbic acids are used in an amount of at least 0.01 % (w/w), preferably in the range of 0.1 to 99% (w/w), more preferably 1 to 99% (w/w), and most preferably, 5 to 99% (w/w) in terms of the weight of L-ascorbic acid against the total weight of the composition.

That is, the amount of L-ascorbic acid in the composition, which L-ascorbic acid is present in the saccharide derivative of L-ascorbic acid, is present in an amount ranging from about 0.01% (w/w) of the entire composition. It is clear from the specification that the amount of L-ascorbic acid is the amount of L-ascorbic acid residue contained in the L-ascorbic acid derivative. For example, L-ascorbic acid 2-glucoside, one of the saccharide derivatives of L-ascorbic acid that can be used in the herein claimed composition, consists of an L-ascorbic acid

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residue and a glucose residue. The amount of saccharide derivative of L-ascorbic acid for purposes of the herein claimed composition I defined in terms of the weight of the L-ascorbic acid residue contained in the saccharide derivative of L-ascorbic acid.

Art Rejections

Claims 17, 20 and 27-31 are rejected under 35 U.S.C. 102(a) as being anticipated by Miyata et al., JP 2003-171290 as evidenced by Takimoto et al., JP 10-147514 or Yonekura et al., JP 09-315928. The Examiner states that Miyata discloses a method for making a collagen production potentiator capable of continuously exhibiting an action of potentiating collagen production using a composition comprising L-ascorbic acid and royal jelly as an active ingredient. The Examiner states that royal jelly inherently contains 10-hydroxy-2-decenoic acid as evidenced by the disclosures of Takimoto and Yonekura.

This rejection is respectfully traversed.

Claims 17 and 31 have been amended to recite that the composition is prepared by mixing (i) an isolated saccharide derivative of L-ascorbic acid and (ii) an isolated 10-hydroxy-2-decenoic acid with (iii) a physiologically acceptable carrier.

Experiment 1 describes isolation of the 10-hydroxy-2-decenoic acid from royal jelly and the finding that 10-hydroxy-2-decenoic acid was the active ingredient in royal jelly that enhances collagen production. That is, even though 10-hydroxy-2-decenoic acid may be present in royal jelly, it is specifically 10-

hydroxy-2-decenoic acid that provides the collagen-enhancing properties and thus is the active ingredient in the presently claimed composition.

Experiment 3 describes the influence of 10-hydroxy-2-decenoic acid on enhancing collagen production with L-ascorbic acid. It should also be noted that saccharide derivatives of L-ascorbic acid tended to exhibit a more distinct enhancement of collagen production when used with 10-hydroxy-2-decenoic acid than other derivatives of L-ascorbic acid.

In contrast thereto, Miyata discloses enhancing collagen production using royal jelly as the active ingredient. It is respectfully submitted that the present inventors have demonstrated that isolated 10-hydroxy-2-decenoic acid is superior to royal jelly, even though royal jelly contains 10-hydroxy-2-decenoic acid, because the isolated 10-hydroxy-2-decenoic acid is not contaminated with other ingredients that may interfere with collagen production or cause adverse reactions to the person to whom the composition is administered.

Claims 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyata as evidenced by Takimoto and Yonekura and further in view of Yamaguchi et al., JP 2000-159656. The Examiner states that Yamaguchi teaches cosmetic compositions having collagen synthesis accelerating effect that are excellent in stability and provide cosmetic excellence in wrinkle prevention and that the composition comprises an ascorbic acid derivative and hyaluronic acid.

This rejection is respectfully traversed.

As noted above, claims 17 and 31, from which claims 26 and 32, respectively depend, have been amended to recite that the composition contains an isolated saccharide derivative of L-ascorbic acid and an isolated 10-hydroxy-2-decenoic acid.

There is nothing in Yamaguchi that teaches mixing (i) an isolated saccharide derivative of L-ascorbic acid with (ii) an isolated 10-hydroxy-2-decenoic acid to enhance collagen production by the saccharide derivative of L-ascorbic acid.

As shown on page 23, lines 4-14 of the instant specification, and Figure 3, 10-hydroxy-2-decenoic acid has a significantly greater enhancing action of collagen production by a saccharide derivative of L-ascorbic acid than other fatty acids, such as 10-hydroxydecenoic acid, 2-decenoic acid, decanoic acid, and sebacic acid. It would have been difficult even for one of ordinary skill in the art to expect that the collagen production by a saccharide derivative of L-ascorbic acid is significantly enhanced when the saccharide derivative of L-ascorbic acid is mixed with 10-hydroxy-2-decenoic acid rather than another fatty acid.

Claims 17, 20 and 26-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yamaguchi combined with Masukaru, JP 09-030921 and further combined with Yonekura, JP 09-315928. The Examiner

states that Masukaru teaches compositions for treating dermal stains of aging by using specific derivatives of L-ascorbic acid. The composition further contains a rutin derivative. Yonekura is said to teach compounds of royal jelly origin comprising 10-hydroxy-2-decenoic acid, decanoic acid, 2-decenoic acid, sebacic acid. These compounds are said to inhibit tyrosinase activity to control generating melanin and provide a skin whitening cosmetic.

This rejection is respectfully traversed.

As noted above, the present specification has demonstrated that 10-hydroxy-2-decenoic acid is superior to the other fatty acids present in royal jelly in its enhancement of collagen production when combined with L-ascorbic acid saccharide derivatives. Accordingly, including other fatty acids obtained from royal jelly rather than 10-hydroxy-2-decenoic acid would not produce the same collagen enhancing effects.

The present applicants have discovered that one particular compound in royal jelly, namely, 10-hydroxy-2-decenoic acid, produces improved collagen enhancing effects when combined with saccharide derivatives of L-ascorbic acid. There is nothing in any of the cited patents that suggests using this particular acid in combination with a saccharide derivative of L-ascorbic acid would produce improved collagen production. Accordingly, it is respectfully submitted that the herein claimed composition is not obvious over any

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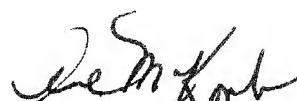
combination of the cited references. Withdrawal of the rejections is earnestly solicited.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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